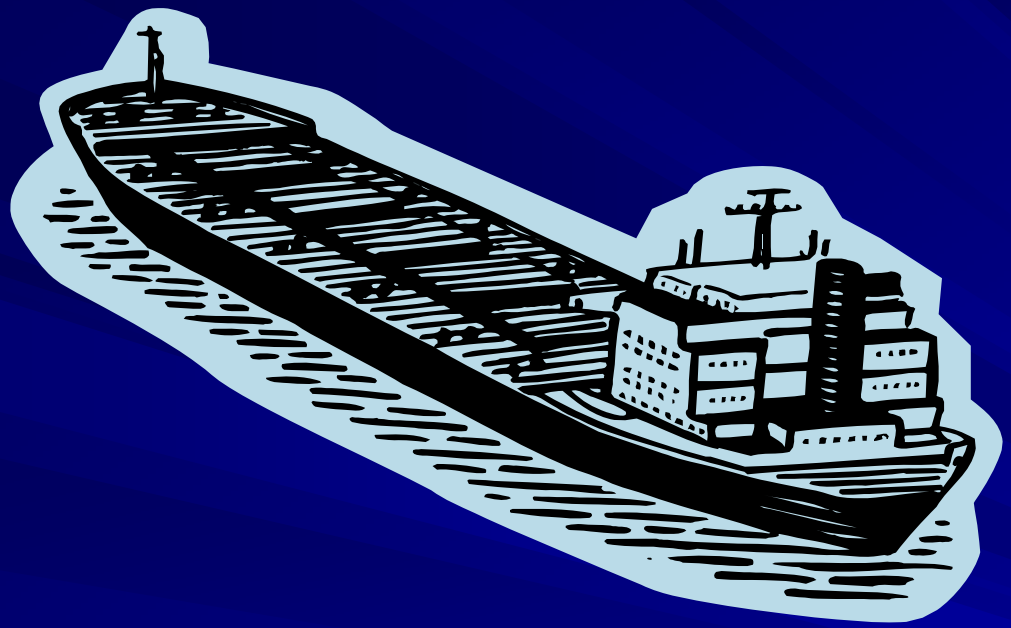
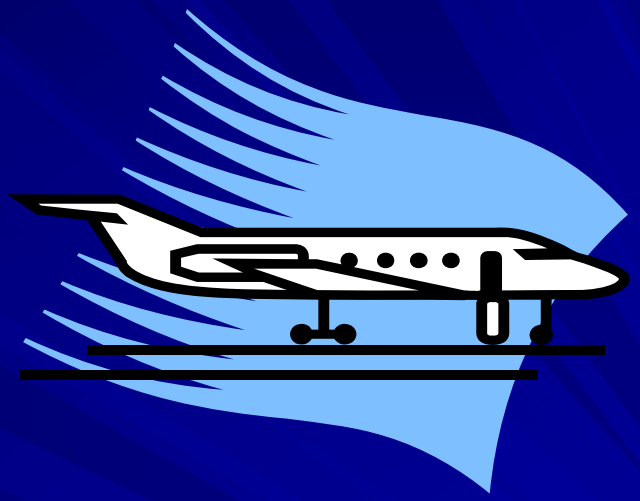
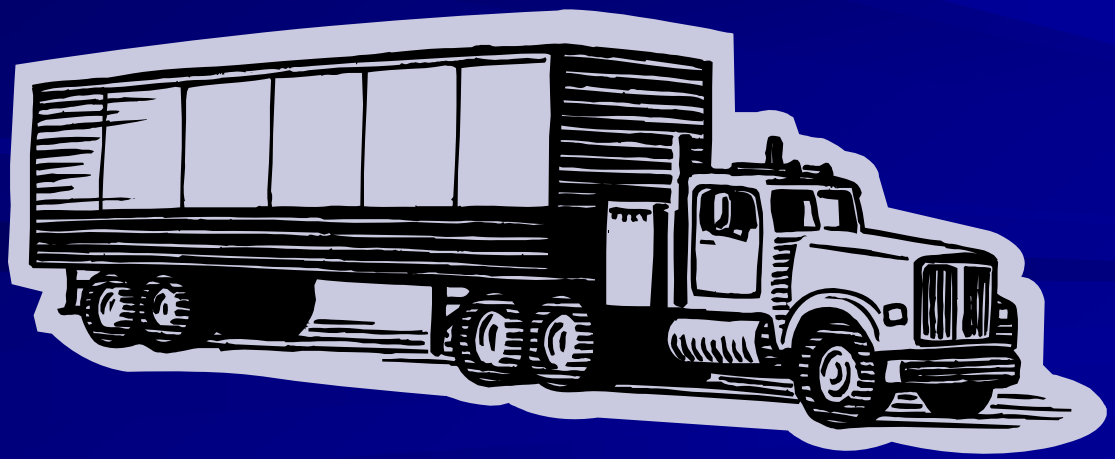
# FOOD ENTRY REVIEW

January 16, 2008

# The Process Begins







# 801 (a) Admissibility

The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States ….. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 520(f), or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 505, then such article shall be refused admission, except as provided in subsection (b) of this section.

http://www.fda.gov/opacom/laws/fdcact/fdcact8.htm

# ELECTRONIC FILING


**OASIS – Operational and Administrative System for Import Support**

- FDA's system used to receive, input, review and process FDA regulated imported products.
- Designed to provide uniform screening of FDA products nationwide.
- Presents screening criteria to entry reviewers to assist with 801 (a) admissibility.

# HTSUS FD FLAGS

When entry data is transmitted through ABI, ACS checks the HTSUS number submitted for OGA flags

- FD0 – The commodity is regulated, however, FDA has waived the requirement of entry notification

- FD1 - Some products MAY require FDA data, other's may not. Filers must either submit FDA data, or DISCLAIM the product.

# HTSUS FD FLAGS

- FD2 - All products within the tariff category require FDA data submission.
- FD3 – All products within the tariff category require FDA data submission and MAY be subject to PN requirements.
- FD4 - All products within the tariff category require FDA data submission and ARE subject to PN requirements.

# FDA REGULATED OR DISCLAIM

- If the product is regulated by FDA, filers MUST submit the regular data set required by CBP as well as the specifically required FDA dataset.
- If the product is NOT regulated by FDA, filers must disclaim the transaction.

# REQUIRED FDA DATA

- Commercial Description
- FDA Manufacturer
- FDA Shipper
- FDA Country of Origin
- FDA Product Code

# OPTIONAL FDA DATA

- Affirmation of Compliance
- Quantity
- Value
- Broker Contact

# AFFIRMATION OF COMPLIANCE

- Optional
  - Not applicable to all products
  - Not required, even when applicable
- Benefit of Use
  - May result in “May Proceed”
    - Low Value Shipments
    - Products requiring FD-2877
  - May speed review process by FDA

# FDA PRODUCT CODES

**Product Code Tutorial**

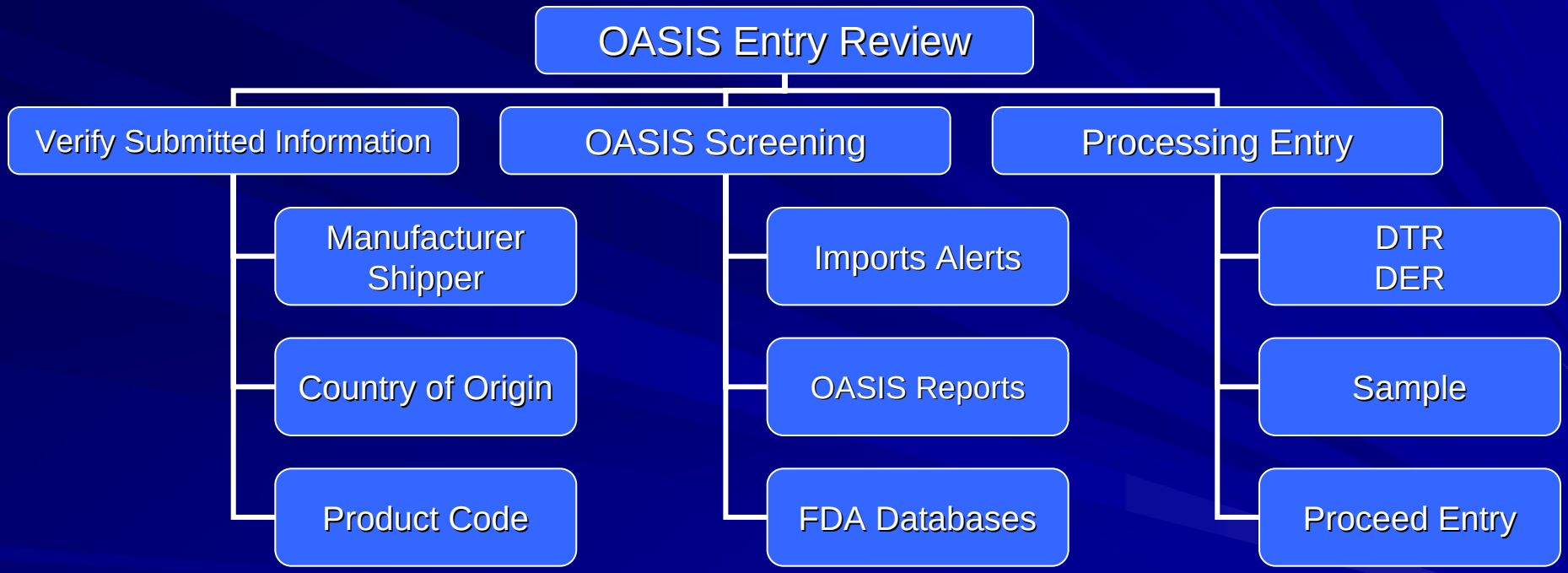
http://www.accessdata.fda.gov/scripts/ora/pcb/tutorial/tutorial.cfm

# Data Accuracy Verification

- Filer Evaluation
- 2 Types of Filers
- Phase 1 & Phase 2
- **Phase 1**
- “Paper Filers”
- NY Dist. 100% Review
- **Phase 2**

  Electronic Filers

# OASIS ENTRY REVIEW



# VERIFYING SUBMITTED INFORMATION

- Compare paperwork and electronic transmission for discrepancies
  a) manufacturer and shipper are correctly submitted
  b) valid Country of Origin was submitted
- Verify correct Product Code was submitted
- OASIS reviews submitted information and recommends courses of action that the investigator may take

# IMPORT ALERTS (IA)

- FIARS (FDA Import Alert Retrieval System)
  - Live data guidance of problems affecting imported products
  - Linked to OASIS based on accurate data transmission.

- Redacted version available online

  http://www.fda.gov/ora/fiars/ora_import_alerts.html

- Import Alert Structure
  a) Import Alert lists firms that are exempt from the alert
  b) Import Alert lists firms that are subject to the alert

# Firms Search

- Prior Shipments

  a) Firm “search” on historical / Intel data concerning specific manufacturer, shipper, consignee, importer

  b) Yields shipment histories

  c) Compliant or Violative past

  d) “Port Shopping”

# Firms Search

## Prior Samples

a) Firm search yields previous samples collected from a specific manufacturer, shipper, consignee, importer

b) Yields lab analysis results for samples and timeframe of when product was last sampled

# PROCESSING ENTRIES

Reviewers have the following courses of action to take on a particular entry:

- Documents Required
- Incomplete Entry requesting additional documents and/or information from filer
- Examination/Sample Collection
- Process a Recommendation for Detention
- May Proceed / Release Entry

# How Do FDA Reviewers Choose What to Examine?

- High Risk Food Commodities
- Historical data / Current Intelligence (or lack of)
- Import Alerts / Import Bulletins
  - 2 types, “good guys” and “bad guys”
- Shipment Inconsistencies
  - Documents vs. Electronic vs. what is on the truck
- Program Obligations

http://www.cfsan.fda.gov/~comm/cp-toc.html

# LACF/AF

**High Risk Food Commodity**

Under or Inadequate Processing can lead to C. Bot. formation

# LACF/AF Regulations

- The registration and process filing regulation for thermally processed low-acid foods packaged in hermetically sealed containers is **21 CFR 108.35**

- The applicable registration and process filing regulation for acidified foods is **21 CFR 108.25**

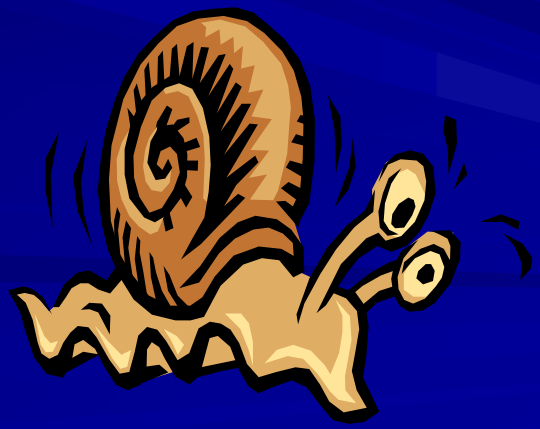
# LACF/AF Foods

- Low acid foods are foods packaged in hermetically sealed containers, which can be metal cans, glass, or plastic pouches, have a pH greater than 4.6 and a water activity greater than0.85.

- Acidified foods must also have a water activity greater than 0.85 to be included under the regulations.

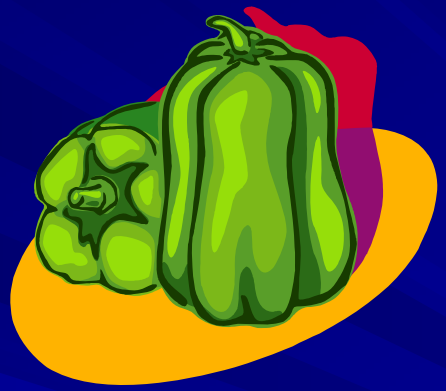
# Examples of LACF Foods

- Most vegetables and fish, i.e.:
  - Bamboo Shoots
  - Water Chestnuts
  - Black Olives
  - Mushrooms
  - Tuna
  - Snails
  - Peas
  - Bean Sprouts
  - Various soups



# Examples of Acidified Foods

- Artichokes
- Hearts of Palm
- Peppers
- Pimientos
- Banana Puree



# IS IT LACF/AF?

- Product name
  - Pickled, marinated, preserved, sour, salad, sauce usually means AF
  - Salted, preserved, sweet, ‘in syrup’ usually means $a_w$ controlled LACF
  - Preserved, pickled, could mean fermented
- Containers
  - Cans usually hold LACF
  - Jars usually hold AF (European countries like their low-acid vegetables in jars)
  - Pouches usually hold LACF
  - Paperboard containers usually hold acid foods, but can be used for LACF/AF

# Information Needed for Entry Review

- FCE Number
- Site specific Manufacturer/Packer name and address
- SID Number and/or can dimensions for the line specific product(s) on entry
  - Can dimensions must be in 16$^{th}$ of an inch.

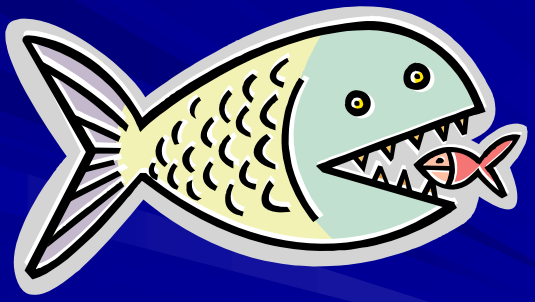
# SEAFOOD

Fin Fish

Scombrotoxic Fish species

Crustaceans

Shellfish

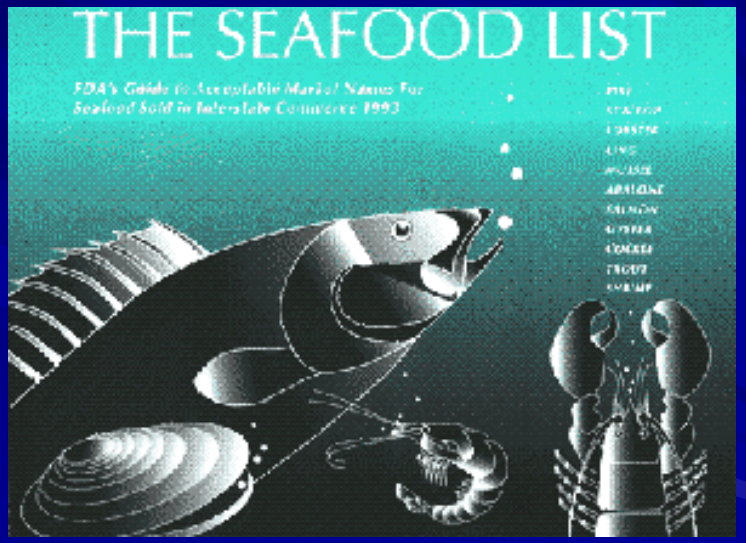


In General

- High Risk
- Perishable
- Decomposition / Microbial Growth
- Chemotherapeutics
- Sulfites
- Pesticides

# THE SEAFOOD LIST

- A compilation of existing, acceptable market names for imported and domestically available seafood
  - market names
  - common names
  - scientific name
  - vernacular name




http://www.cfsan.fda.gov/~frf/seaintro.html

# THE SEAFOOD LIST

Purpose of the List

- Promote uniformity in the marketplace
- Reduce consumer confusion
- Help identify hazardous species
- Discourages economic deception

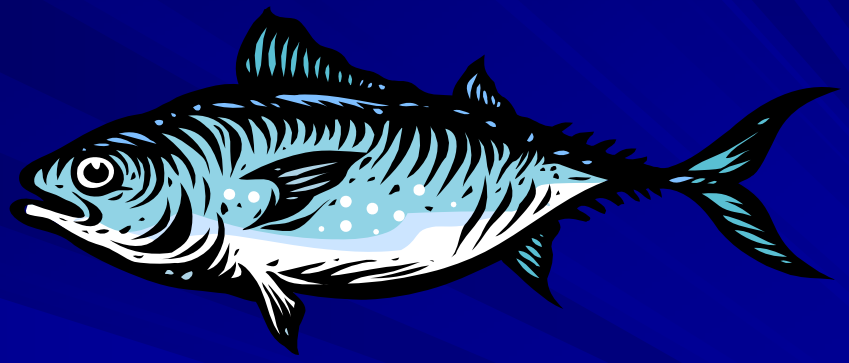
Import Alert 16-04  Misbranded Seafood Products
Import Alert 16-128  Misbranded Catfish

# Scombrotoxic Fish

- Bacterial Decomposition begins upon death of fish.
- Time / Temperature abuse promote bacterial growth
- Toxin Formation / Histamine / Poisonings / Illness
- All Humans are Susceptible

# Scombrotoxic Fish

- Mahi
- Tuna
- Escolar
- Marlin
- Wahoo
- Amber Jack
- Jack
- Bonito
- Bluefish
- Mackerel
- Herring, Anchovy, Sardines



http://seafood.ucdavis.edu/haccp/compendium/Table%203-1.htm

# SHELLFISH

- Work with individual States to regulate.
- INTERSTATE CERTIFIED SHELLFISH SHIPPERS LIST Available Online at: http://www.cfsan.fda.gov/~ear/shellfis.html
- Covers shellfish (all edible species of oysters, clams, mussels, and scallops*; either shucked or in the shell, fresh or frozen, whole or in part). *scallops are to be excluded when the final product is the shucked adductor muscle only.

# CHEESE

- Three categories of cheese: Soft, Semi-soft, Hard
- If source of cheese is from something other than a cow, the cheese is required to be named by that source on the labeling.
- Cheese Standards of Identity
  - 21 CFR 133.182 - soft, ripened cheese
  - 21 CFR 133.187 - semi-soft cheese
  - 21 CFR 133.150 - hard cheese

**If cheese has no standard of identity, it must be made from pasteurized milk.**

- Aging requirements

  If cheese is not made from pasteurized milk, the cheese must be aged for at least 60 days at a temperature not lower than 35ºF.
- Labeling Requirements for Cheeses
  1. Name of the Cheese
  2. Statement if made from pasteurized or raw milk
  3. Aged / Cured, duration of process
  4. Date coding
  5. Ingredients
  6. Nutritional Labeling

# IMPORT ALERTS PERTAINING TO CHEESE

- Import Alert 12-03 DWPE of Imported Soft Cheese due to L. monocytogenes
- Import Alert 12-07 DWPE of Imported Cheese from Azores / Portugal
- Import Alert 12-10 DWPE of Imported Cheese due to Salmonella, E. coli and S. aureus
- Import Alert 12-12 DWPE of Imported Cheese containing Nitrates

# Fresh Produce

- Commodities Associated with Foodborne Illness
- Commodities / Manufacturers Associated with Pesticide contamination.
- Surveillance Programs
- Always Expedited Sample Analysis
- USDA Perishable List

# U.S. GOODS RETURNED

Must Clearly Identify the commodity on Electronic data and supporting entry docs.

Minimal info required by CBP. All USGR (9801) Flagged FD03

Why? What are the circumstances surrounding?

# PROCEEDING ENTRIES

Issue May Proceed for Entry

- ✓ information submitted properly
- ✓ product(s) not associated with IA
- ✓ no sample collection is necessary, product not High Risk and/or recently sampled and was non-violative
- ✓ product/manufacturer properly listed in FDA databases
- ✓ Program needs met?

# BIGGEST PROBLEM ENCOUNTERED WITH ENTRY REVIEWAT THE TIME OF ENTRY

INFORMATION, INFORMATION, INFORMATION!!

- Incomplete information provided
- Incorrect information provided
- NO information provided

# References

- Food Drug and Cosmetic Act
  http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm
- Title 21 Code of Federal Regulations
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
- Investigations Operations Manual
  http://www.fda.gov/ora/inspect_ref/IOM/default.htm
- Compliance Policy Guides
  http://www.fda.gov/ora/compliance_ref/cpg/default.htm
- Regulatory Procedures Manual
  http://www.fda.gov/ora/compliance_ref/rpm/default.htm
- Compliance Program Guidance Manual
  http://www.cfsan.fda.gov/~comm/cp-toc.html
- Memorandum of Understanding
- Field Management Directives
  http://www.fda.gov/ora/inspect_ref/fmd/default.htm

# The End